IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of : Marc Bohner et al.	)	Confirmation No. 2019
	)	
	)	Group Art Unit: 3733
Serial No.: 10/597,502	)	
	)	Examiner: Jan Christopher Merene
	)	
Filed: July 27, 2006	)	
	)	
Title: INJECTION DEVICE, ESPECIALLY FOR BONE CEMENT	)	
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Atty. Dkt.: LUS-16768	)	
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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPELLANTS' BRIEF (37 CFR § 41.37)

Applicant is submitting an Appellants Brief. Authorization for payment to cover the fee referenced in 37 CFR 41.20(b)(2) is provided. If any additional fees are due in combination with this filing, please charge such additional required fees to our Deposit Account No. 18-0160, our Order No. LUS-16768.

This brief contains the items under the following headings in the order set forth below:

I. REAL PARTY IN INTEREST

II. RELATED APPEALS AND INTERFERENCES

III. STATUS OF CLAIMS

IV. STATUS OF AMENDMENTS

V. SUMMARY OF CLAIMED SUBJECT MATTER

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

VII. ARGUMENTS

VIII. CLAIMS APPENDIX

IX. EVIDENCE APPENDIX (none)

X. RELATED PROCEEDINGS APPENDIX (none)

I. REAL PARTY IN INTEREST

Dr. H.C. Robert Mathys Stiftung, having a place of business at Bischmattstrasse 12, Bettlach, Switzerland CH-2544 is the real party in interest and the assignee of all right, title, and interest to the invention throughout the world. An assignment from inventors Marc Bohner and Paul Heini has been recorded with the United States Patent and Trademark Office and can be found at Reel 018017 and Frame 0365.

II. RELATED APPEALS AND INTERFERENCES

Applicant does not know of any related appeals and/or interferences that will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

A. Total Number of Claims in Application

Ten claims are currently pending in this application.

B. Status of the Claims

1. Claims previously canceled: Claims 2-4, 8, and 11-12.

2. Claims withdrawn from consideration but not cancelled: None.

3. Claims pending: Claims 1, 5-7, 9-10 and 13-16.

4. Claims allowed: None.

5. Claims rejected: Claims 1, 5-7, 9-10 and 13-16.

6. Claims objected to: None.

7. Claims indicated as allowable if the § 112 rejections are overcome: None.

C. Claims on Appeal

The claims on appeal are: Claims 1, 5-7, 9-10 and 13-16.

IV. STATUS OF AMENDMENTS

A Response to the Final Office Action of February 27, 2009 was filed on May 27, 2009. The Examiner, as noted in an Advisory Action of June 30, 2009, did not enter the proposed amendments for purposes of appeal. The Examiner maintains a rejection of Claims 1, 5-7, 9-10 and 13-16.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Independent Claim 1

The invention claimed in independent claim 1 relates to an injection device 1, especially for bone cement. (Specification paragraph [0001]; Fig. 1) The syringe body 3 has a longitudinal axis 2, a front end 6, and a connecting piece 8 which is disposed at the front end 6 and has a coaxial borehole 21 and a coaxial cavity 4. (Specification paragraphs[0019]-[0020]; Fig. 1) The injection device 1 also includes an injection piston 5 which can be shifted coaxially in the cavity 4. (Specification paragraph [0019]; Fig. 1) The injection device also includes a cannula 13, which can be connected with the connecting piece 8 with a central borehole 14 and a rear end 15. (Specification paragraph [0020]; Fig. 1) The front end 6 of the syringe body 3 has a transition segment 22 with a coaxial borehole 9 with constant diameter, connecting the cavity 4 with the borehole 21 in the connecting piece 8. (Specification paragraph [0020]; Fig. 1) The borehole 9 in the transition segment 22 and the central borehole 14 have the same cross-sectional area orthogonal to the longitudinal axis 2 at least at the rear end of the cannula 13. (Specification paragraph [0020]; Figs 1 and 2) The central borehole 14 of the cannula 13 has a constant cross sectional area q in the axial direction. (Specification paragraph [0020]; Figs. 1 and 2) The cavity 4 has a cross-sectional area Q, which is orthogonal to the longitudinal axis 2 and the ratio of the cross sectional areas q:Q is between 0.200 and 0.033 (Specification paragraph [0020]; Figs. 1 and 2)

Dependent claim 7 (separately argued)

The invention claimed in dependent claim 7 (depends from claims 1, 5 and 6) relates additionally to the bore 9 having an internal thread 10 in the connecting piece 8.

(Specification paragraphs [0019]-[0020] Fig. 1) The cannula 13, at the rear end 15, comprises an external thread for screwing the cannula into the internal thread, and the external thread is complementary to the internal thread (Specification paragraph [0019] and [0020] Fig. 1)

VI. GROUNDS OF REJECTION

1. Whether claims 1, 5-6, 9-10 and 13-16 are patentable under 35 U.S.C. § 103(a) over U.S. Patent No. 4,220,151 to Whitney.

2. Whether claim 7 is patentable under 35 U.S.C. § 103(a) over U.S. Patent No. 4,220,151 to Whitney.

3. Whether claim 1 is patentable under 35 U.S.C. § 103(a) over U.S. Patent No. 4,815,454 to Dozier.

4. Whether claims 5-6, 8-10 and 13-16 are patentable under 35 U.S.C. § 103(a) over U.S. Patent No. 4,815,454 to Dozier in view of U.S. Patent No. 4,220,151 to Whitney.

5. Whether claim 7 is patentable under 35 U.S.C. § 103(a) over U.S. Patent No. 4,815,454 to Dozier in view of U.S. Patent No. 4,220,151 to Whitney.

VII. ARGUMENTS

1. The Rejection of claims 1, 5-6, 9-10 and 13-16 under 35 U.S.C. § 103(a) over U.S. Patent No. 4,220,151 to Whitney.

In order to establish a prima facie case of obviousness under 35 U.S.C. §103, the cited references must teach each and every claim limitation or element of the rejected claims. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). The rejection of independent claim 1 and dependent claims 5-6, 9-10 and 13-16 should be reversed, because each and very limitation of the claimed invention is not taught or suggested by Whitney.

Whitney does not teach or suggest all of the features of amended claim 1. Specifically, claim 1 requires "a cannula which can be connected with the connecting piece". Whitney does not teach such a cannula. Rather, the conical section of the Luer-lock connection in Whitney, which the Examiner refers to as the cannula, is integrally formed with the syringe body of Whitney and thus is not a cannula "which can be connected with a connecting piece". Simply because this portion of the syringe body in Whitney may be broken off does not make it a cannula that can be connected with a connecting piece.

Further, claim 1 requires that the central borehole of the claimed cannula "has a constant cross-sectional area q in the axial direction". Referring to Fig. 2 of Whitney, the section of the Luer-lock connection referred to by the Examiner is conical, and thus, does not have a constant cross sectional area in the axial direction.

Applicant concludes that the prior art rejections of the cited claims should be reversed because the cited reference does not teach or suggest all of the features of

the claim. Specifically, the rejection of claims 1, 5-6, 9-10 and 13-16 as being unpatentable over Whitney is in error.

2. The Rejection of dependent claim 7 under 35 U.S.C. § 103(a) over U.S. Patent No. 4,220,151 to Whitney.

In order to establish a prima facie case of obviousness under 35 U.S.C. §103, the cited references must teach each and every claim limitation or element of the rejected claims. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). The rejection of independent claim 1 and dependent claims 5-6, 9-10 and 13-16 should be reversed, because each and very limitation of the claimed invention is not taught or suggested by Whitney.

Whitney discloses a Luer-lock connection, which by definition does not meet the requirements of claim 7. A Luer-lock connection does not include exterior threads anywhere therein, but rather exterior tabs on one portion of the connection. In Whitney, these tabs (or ears) are labeled 48 and 50. A replacement of these tabs by an external thread would not allow a break away disconnection of the connector 28 form the barrel 18 which is required by Whitney (see row 4, lines 39-45) and thus Whitney teaches away from such a variation.

Applicant concludes that the prior art rejections of the cited claims should be reversed because the cited reference does not teach or suggest all of the features of the claim. Specifically, the rejection of claim 7 as being unpatentable over Whitney is in error.

3. The Rejection of Claim 1 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,815,454 to Dozier.

In order to establish a prima facie case of obviousness under 35 U.S.C. §103, the cited references must teach each and every claim limitation or element of the rejected claims. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). The rejection of independent claim 1 should be reversed, because each and very limitation of the claimed invention is not taught or suggested by Dozier.

Claim 1 requires:

A) a syringe body (3) with a longitudinal axis (2), a front end (6), a connecting piece (8), disposed at the front end (6) and having a coaxial borehole (21), and a coaxial cavity (4);

C) a cannula (13), which can be connected with the connecting piece (8), with a central borehole (14) and rear end (15); wherein

D) the front end (6) of the syringe body (3) has a transition segment (22) with a coaxial borehole (9) with constant diameter, connecting the cavity (4) with the borehole (21) in the connecting piece (8); and wherein

E) the borehole (9) in the transition segment (22) and the central borehole (14) have the same cross-sectional area orthogonal to the longitudinal axis (2) at least at the rear end (15) of the cannula (13);

The nozzle 22 of Dozier does not fulfill the requirements of the claimed cannula because the nozzle includes a cap portion 21. This cap portion has a bore diameter that does not match the bore diameter of any other element of the Dozier

device. This is because threads fit into the bore diameter of the cap portion of Dozier. Thus there can be no bore hole in a transition segment in Dozier that has the same diameter as the central borehole in the cannula, at the rear end of the cannula, as required by claim 1.

Rebutting an alternate interpretation of Dozier, the cap portion 21 of the nozzle 22 in Dozier can not be considered the same as the claimed connecting element of claim 1, because the cap portion is not part of a syringe body as is required by claim 1, but rather is integrally formed with the nozzle in Dozier as is clearly seen in Fig. 5. Thus, Dozier does not teach a cannula that can be connected to a cap portion of a syringe body.

Claim 1 also requires that the central borehole of the cannula have a constant cross sectional area q in the axial direction. However, because of the presence of the cap portion of the nozzle in Dozier, the cross sectional area of the nozzle or cap portion does not remain constant.

Claim 1 also requires: a cavity (4) that has a cross-sectional area Q, which is orthogonal to the longitudinal axis (2) and that the ratio of the cross sectional areas q : Q is between 0.200 and 0.033. This results in an injection force which is as low as possible making the device simple to use.

Dozier fails to teach or suggest the required ratio of cross sections.

Applicant concludes that the prior art rejections of the cited claims should be reversed because cited reference does not teach or suggest all of the features of the claim. Specifically, the rejection of claim 1 as being unpatentable over Dozier is in error.

4. The Rejection of Claims 5-6, 8-10 and 13-16 under 35 U.S.C. § 103(a) over U.S. Patent No. 4,815,454 to Dozier in view of U.S. Patent No. 4,220,151 to Whitney.

In order to establish a prima facie case of obviousness under 35 U.S.C. §103, the cited references must teach each and every claim limitation or element of the rejected claims. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). The rejection of independent claim 1 should be reversed, because each and very limitation of the claimed invention is not taught or suggested by Dozier and Whitney.

Claim 5 depends from claim 1 and requires: a cavity (4) that has a cross-sectional area Q, which is orthogonal to the longitudinal axis (2) and that the ratio of the cross sectional areas q : Q is between 0.200 and 0.033. This results in an injection force which is as low as possible making the device simple to use.

Both Dozier and Whitney fail to teach or suggest the required ratio of cross sections.

Claim 5 (from claim 1) also requires that the central borehole of the cannula have a constant cross sectional area q in the axial direction. Referring to Fig. 2 of Whitney, the section of the Luer-lock connection referred to by the Examiner is conical, and thus, does not have a constant cross sectional area in the axial direction. Because of the presence of the cap portion of the nozzle in Dozier, the cross sectional area of the nozzle or cap portion does not remain constant.

Applicant concludes that the prior art rejections of the cited claims should be reversed because cited references do not teach or suggest all of the features of the

claims. Specifically, the rejection of claims 5-6, 8-10 and 13-16 as being unpatentable over Dozier in view of Whitney is in error.

5. The Rejection of claim 7 under 35 U.S.C. § 103(a) over U.S. Patent No. 4,815,454 to Dozier in view of U.S. Patent No. 4,220,151 to Whitney.

In order to establish a prima facie case of obviousness under 35 U.S.C. §103, the cited references must teach each and every claim limitation or element of the rejected claims. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). The rejection of dependent claim 7 should be reversed, because each and very limitation of the claimed invention is not taught or suggested by the combination of Dozier and Whitney.

Whitney discloses a Luer-lock connection, which by definition does not meet the requirements of claim 7. A Luer-lock connection does not include exterior threads anywhere therein, but rather exterior tabs on one portion of the connection. In Whitney, these tabs (or ears) are labeled 48 and 50. A replacement of these tabs by an external thread would not allow a break away disconnection of the connector 28 form the barrel 18 which is required by Whitney (see row 4, lines 39-45) and thus Whitney teaches away from such a variation.

Dozier also fails to teach external threads on a cannula. Rather, Dozier teaches a tubular nozzle with an internal thread on a cap portion and a plunger with an external thread. Neither references teaches a cannula with an external thread.

Reversal of the device parts in Dozier also would not be an obvious variation. Because the elements 19 and 21 in Dozier are not similar, these components of the

device in Dozier would also need to be resize and reconfigured completely (the size and the configuration of parts 19 and 22 would need to change) in order for the device of Dozier to function ins a usable manner. Complete reconfiguration and resizing would not be an obvious variation of the device taught by Dozier.

Applicant concludes that the prior art rejections of the cited claims should be reversed because cited references do not teach or suggest all of the features of the claims. Specifically, the rejection of claim 7 as being unpatentable over Dozier in view of Whitney is in error.

Conclusion

The prior art rejections of the cited claims should be reversed because the cited references either do not disclose the invention fully or are not properly combinable.

For the reasons set for the herein, the rejections of the claims 1, 5-7, 9-10 and 13-16 of the present application are in error and must be reversed.

Respectfully submitted,

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Date: October ____, 2009

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VII. CLAIMS APPENDIX

1. (Previously Presented) An injection device (1) especially for bone cement, comprising:

A) a syringe body (3) with a longitudinal axis (2), a front end (6), a connecting piece (8), disposed at the front end (6) and having a coaxial borehole (21), and a coaxial cavity (4);

B) an injection piston (5), which can be shifted coaxially in the cavity (4); and

C) a cannula (13), which can be connected with the connecting piece (8), with a central borehole (14) and rear end (15); wherein

D) the front end (6) of the syringe body (3) has a transition segment (22) with a coaxial borehole (9) with constant diameter, connecting the cavity (4) with the borehole (21) in the connecting piece (8); and wherein

E) the borehole (9) in the transition segment (22) and the central borehole (14) have the same cross-sectional area orthogonal to the longitudinal axis (2) at least at the rear end (15) of the cannula (13);

F) the central borehole (14) of the cannula (13) has a constant cross-sectional area q in the axial direction; and

G) the cavity (4) has a cross-sectional area Q, which is orthogonal to the longitudinal axis (2) and that the ratio of the cross sectional areas q : Q is between 0.200 and 0.033.

5. (Previously Presented) The injection device (1) of claim 1, wherein the borehole (9) has an internal thread (10) in the connecting piece (8).

6. (Previously Presented) The injection device (1) of claim 5, wherein the cannula (13) at the rear end (15) comprises means (16) for screwing the cannula (13) into the internal thread (10).

7. (Previously Presented) The injection device (1) of claim 6, wherein the means (16) are an external thread, which is complementary to the internal thread (10).

9. (Previously Presented) The injection device (1) of claim 5, wherein the diameter of the borehole (9) in the transition segment (22) and the geometry of the internal thread (10) in the connecting piece (8) correspond to those of a luer lock connection.

10. (Previously Presented) The injection device (1) of claim 6, wherein the means (16) for screwing into the internal thread (10) are constructed as a luer lock adapter.

13. (Previously Presented) The injection device (1) of claim 6, wherein the diameter of the borehole (9) in the transition segment (22) and the geometry of the internal thread (10) in the connecting piece (8) correspond to those of a luer lock connection.

14. (Previously Presented) The injection device (1) of claim 7, wherein the diameter of the borehole (9) in the transition segment (22) and the geometry of the internal thread (10) in the connecting piece (8) correspond to those of a luer lock connection.

15. (Previously Presented) The injection device (1) of claim 7, wherein the means (16) for screwing into the internal thread (10) are constructed as a luer lock adapter.

16. (Previously Presented) The injection device (1) of claim 9, wherein the means (16) for screwing into the internal thread (10) are constructed as a luer lock adapter.

IX. EVIDENCE APPENDIX (none)

X. RELATED PROCEEDINGS APPENDIX (none)